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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,326	09/18/2000	Paul Habermann	02481.1693	4393

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EXAMINER
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SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/664,326	HABERMANN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Holly Schnizer	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

The Response filed 3/16/06 has been entered and considered. Claims 6-9 are currently pending and have been considered in this Office Action.

### ***Rejections Maintained***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### ***Response to Applicants arguments:***

Applicants argue that because the E. coli strain Mc1061 is not an E. coli secretor mutant, Applicants were in possession of the methods instantly claimed and further that "[I]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims." (citing MPEP 2173.05(i) and *In re Johnson*, 558 F.2d 1008, 1019 194 USPQ 187, 196 (CCPA 1977)). This argument has been considered but is not deemed persuasive for the following reasons. As explained in the previous Office

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Action and below, while the specification mentions E. coli strain Mc1061, the specification does not indicate which E. coli strain (Mc1061 or WCM100) was used in the disclosed tests and which gave the expression that was 1.5 times better than the comparative test (Ala-hirudin expression using WCM100/pCM7053); page 9, lines 23-24, page 10, lines 18-20, and page 11, lines 19-20 all again refer to expression of hirudin with different signal peptides as compared to Ala-hirudin expression using the E. coli strain WCM100/pCM7053. Moreover, unlike the case described in MPEP 2173.05(i) or In re Johnson, 558 F.2d 1008, 1019 194 USPQ 187, 196 (CCPA 1977), the present case does not provide a positive recitation for the genus of E. coli strains that are not secretor mutants but only the species of E. coli strain Mc1061. Therefore, while the specification may provide support for using the E. coli strain Mc1061 in the claimed method, it does not support using a genus of E. coli strains that are not secretor mutants. Thus, the rejection is maintained for reasons cited in the previous Office Action and below.

*Rejection:*

The added limitation that the E. coli bacteria used in the process are not E. coli secretor mutants is considered new matter. Applicants contend that support is found in several passages in the Specification which are addressed as follows: page 9, lines 3-5 states that competent cells of the E. coli strain Mc1061 or the secretor mutant WCM100 were transformed with the ligation mixture and grown under selection pressure on ampicillin containing plates and that expression was compared with Ala-hirudin using the E. coli strain WCM100/pCM7053. However, the Specification does not indicate

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which E. coli strain (Mc1061 or WCM100) was used in these tests and which gave the expression that was 1.5 times better than the comparative test (Ala-hirudin expression using WCM100/pCM7053); page 9, lines 23-24, page 10, lines 18-20, and page 11, lines 19-20 all again refer to expression of hirudin with different signal peptides as compared to Ala-hirudin expression using the E. coli strain WCM100/pCM7053. The Specification does not indicate that one E. coli strain would be better than another or that the E. coli strain is of importance. The object of the present Invention is to find a signal sequence that, when combined with Leu-hirudin, will permit direct processing to Leu-hirudin and subsequent secretion of native Leu-hirudin in optimal yields in E. coli in general (see for example p. 2, lines 19-24 and page 3, lines 1-2 which states that in order to find advantageous signal sequences). The Specification as a whole does not teach that the type of E. coli strain is important or that non-secretor mutants should be used. Therefore, since the Specification as a whole teaches that any E. coli strain could be used and is not important to the invention, the negative limitation that the E. coli bacteria are not E. coli secretor mutants is considered new matter. For the reasons stated above, it does not appear that, at the time of filing, Applicant contemplated the exclusion of the genus of E. coli secretor mutants from the process of the invention.

### ***Conclusions***

No Claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Tuesday-Thursday from 10 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Holly Schnizer  
May 29, 2006



KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER